OCT 15 2004

SECTION 11

510(k) Summary of Safety and Effectiveness

Sponsor: Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Iskra Mraković
Manager of Regulatory Affairs
Telephone: (650) 694-5004
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Submission Date: September 22, 2004

Device Name: ACUSON AcuNav 8F Ultrasound Catheter

Common Name: Intracardiac/Intravascular Ultrasound Catheter

Classification:

Regulatory Class: II
Review Category: Tier II

	FR #	Product Code
Diagnostic Intravascular Catheter	870.1200	74-DQO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Predicate Devices:

- # K033650 (February 24, 2004), cleared as ACUSON AcuNav® 90/10 Diagnostic Ultrasound Catheter.
- # K992631 (November 8, 2001), cleared as ACUSON AcuNav® Diagnostic Ultrasound Catheter.
- #K010950 (June 27, 2001), cleared as Cypress Ultrasound System with AcuNav Diagnostic Ultrasound Catheter.

Device Description:

The AcuNav catheter is comprised of a single-use, disposable ultrasonic phased-array imaging transducer and a catheter which is 8 Fr in diameter and 110 cm in insertable length.

The device is capable of imaging at multiple frequencies and obtaining blood flow data in multiple ultrasound modes. The distal portion of the catheter can be deflected in four directions in two orthogonal planes: left-right (in a plane perpendicular to the image plane) and anterior-posterior (in a plane coincident with the image plane). The range of deflection is 160° in each direction. The AcuNav catheter is comprised of three major components: (1) the catheter itself; (2) the steering mechanism; and (3) the reusable system cable.

The AcuNav 8F ultrasound catheter is substantially equivalent to our current product that is already cleared for USA distribution under the following 510(k) PreMarket Notification numbers:

- # K033650 (February 24, 2004), cleared as ACUSON AcuNav 90/10 Diagnostic Ultrasound Catheter.
- # K992631 (November 8, 2001), cleared as ACUSON AcuNav Diagnostic Ultrasound Catheter.
- #K010950 (June 27, 2001), cleared as Cypress Ultrasound System with AcuNav Diagnostic Ultrasound Catheter.

The AcuNav 8F Ultrasound Catheter has been designed to conform to the following *product safety standards* [as required by 21 CFR § 807.87(j)]:

- UL 60601-1, Safety Requirements for Medical Equipment
- EN 60601-1: 1990+A1 (1992) +A2 (1995)
- IEC 60601-2-37: 2001+AM1 (2004)
- CAN/CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- CISPR 11, Class A
- ISO 10555-1: 1995+AM1 (1999)
- EN 60601-1-2: 2001
- EN 55011:1991 (Radiated and Conducted Emissions) - Class A or B, Group 1
- EN 61000-3-2, edition 2.1 (Harmonic Current Emissions)
- EN 61000-3-3:1994, plus AM1 (2001) (Voltage Fluctuations, Flicker Emissions)
- IEC 61000-4-2, edition 1.2 (ESD)
- IEC 61000-4-3, edition 2.1 (Radiated RF)
- IEC 61000-4-4:1995, plus AM1 (2000) and AM 2 (2001) (EFT/Burst)
- IEC 61000-4-5, edition 1.1 (Surge)

- IEC 61000-4-6, edition 2.0 (Conducted RF Immunity)
- IEC 61000-4-8, edition 1.1 (PF Magnetic Fields)
- IEC 61000-4-11, edition 1.1 (Voltage Dips and Interruptions)
- AIUM/NEMA UD-2: 1998: Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3: 1998: Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 1157: Declaration of Acoustic Power
- ISO 10993-1, 2003: Biological evaluation of medical devices - Part 1: Evaluation and Testing
- ISO 10993-7, 1995: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 11135, 1994: Sterilization (Medical devices-Validation and routine control of ethylene oxide sterilization)
- ISO 14971: Medical Devices – Application of Risk Management to Medical Devices
- 93/42/EEC Medical Device Directive

Indications for Use:

The AcuNav™ Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Technological Comparison to Predicate Device:

The AcuNav 8F Ultrasound Catheter is substantially equivalent in its technologies and functionality to the AcuNav 90/10 Diagnostic Ultrasound Catheter that is already cleared under 510(k) premarket notification numbers K033650 (Feb. 24, 2004), K992631 (Nov. 8, 2001), and K010950 (June 27, 2001).

Both, AcuNav 8F and AcuNav 90/10 catheters are ultrasound-tipped catheter devices used directly within the vasculature and/or the heart for intravascular or intracardiac ultrasound imaging, as well as for the measurement of blood flow.

Devices are specifically indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Siemens Medical Solutions USA, Inc.
c/o Dr. Iskra Mraković
Manager, Regulatory Affairs
1230 Shorebird Way
P.O. Box 7393
Mountain View, CA 94039

Re: K042593
Trade Name: ACUSON AcuNav™ 8F Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: September 22, 2004
Received: September 23, 2004

Dear Dr. Mraković:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042593

510(k) Number (if known): _____

Device Name: ACUSON AcuNav™ 8F Ultrasound Catheter

Indications for Use:

The ACUSON AcuNav™ Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K042593

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number_____